UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,756	12/30/2004	Johan Neyts	50304/054001	5115

21559 7590 12/11/2008

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,756	NEYTS ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-50* is/are pending in the application.

4a) Of the above claim(s) *26,27,30-44 and 47-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25,28,29,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/2005;3/23/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 30-44, 47-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, as being drawn to a nonelected species, here being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 2, 2008.

2. Applicant's election with traverse of invention group IG, drawn to method of treating or preventing a diseases comprising administering to a subject a compound defined by the general formula (Z), wherein R1 is aryl group and R3 is 6-membered heterocyclic ring, and the compound species of 2-phenyl-5-(pyridin-4-ylmethyl)-5H-imidazo[4,5-c]pyridine (entry 26 in table 8) in the reply filed on September 2, 2008 is acknowledged. The traversal is on the ground(s) that the restriction requirements do not clearly define whether the R1 and R3 groups are substitute or unsubstituted. This is not found persuasive because absent particular limitation, the R1 and R3 referred in the restriction include both substituted and unsubstituted insofar as within the definition by the application.

The requirement is still deemed proper and is therefore made FINAL.

On further consideration, following species election is required.

3. This application contains claims directed to the following patentably distinct species various virus as recited in claims 24-27. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 23, 28-30, 45 and 46 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. During a telephone conversation with James DeCamp on December 1, 2008 a provisional election was made without traverse to prosecute the species of hepatitis C, claim 25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26 and 27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims Rejections 35 U.S.C. 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-25, 28, 29, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating infection of single strand RNA virus as recited in claims 24 and 26 by using the compound defined general formula (Z), characterized as X s a bond and Y is methylene, does not reasonably provide enablement for A) preventing

such infections or any other disorders, B) treating other disorders, and C) treating the infection by other compounds encompassed by the general formula. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention commensurate in scope with these claims.

7. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claims broadly encompass treating and preventing any diseases (claim 45), particularly, any viral infection with the general formula (Z) characterized by a two linkers X and Y, which may be any one of a variety of moieties, including a single bond, and many substituents encompass a variety of distinct substituents. Viral infections including various distinct virus species and different symptoms. A lot of efforts have been made for preventing viral infection, but met with

little success other than some immunization methods. The application provide certain working examples of in vitro models against the single strand RNA virus, with compounds within the elected invention where Y is single bond, and X is methylene (see table 9 for GPJN-31, GPJN-34, GPJN-35). However, the application provides no working examples, guidance and directions as however the method would be effective for preventing the virus infection. Further, the application fails to provide working examples for treating any other diseases. Furthermore, the application fails to provide working examples, guidance, or rationale that compounds with different linkers or substituents would have been similarly useful as GPJN-31, GPJN-35 and GPJN-35. It is well known in the art that different virus infections would have distinct underline etiologies and would have different therapeutical target. For examples, a therapeutical agent effective for treating HIV infection is not necessarily useful for treating other viral infection, such as herpes or hepatitis virus. Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The variation of the linkers, and substituents in the compound defined by formula (Z) would reasonably change the shape, binding affinity of the compound and thereby change its pharmaceutical properties. The instant claims read on treating and preventing any diseases (claim 45), particularly, any viral infection with the general formula (Z) characterized by a two linkers X and Y, which may be any one of a variety of moieties, including a single bond, and many substituents encompass a variety of distinct substituents, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617